

Meeting Minutes

Subject	SOMs Meeting -- System Evaluation Cegedim Dendrite
Date	Thursday, September 8, 2011
Time	All day
Attendees	Tom Napoli -- Host Robert C. Williamson, Mgr. DEA Consulting--Cegedim Dendrite Jonathan Kuhn, PhD -- Statistical Consultant Scott Soltis, Mary Woods, Larry Schaffer, Justin Park, Laura Pinti, Sandra Simmons, Lisa Scott, Lynn DaCunha, Jaydeep Shukla, Rick Robbins, Napoleon Clarke

Scott: Welcome Guests and Colleagues

Tom: Opening remarks: Introduction of attendees
SOM's Program is labor intensive -- last two years manual process
Systemic approach to next level
Capital Project for 2012 -- supply info from Watson to Cegedim

Agenda (Tom): Overview of organization
Anda not included in scope of this project
Enable and sustain growth of our business --\$498 million of CS products sold in 2010 with 5 top products Hydrocodone, Oxycodone, Fentanyl and Methylphenidate (Concerta P&G)
Enable and sustain growth of business -- Security & Compliance
Systematic upgrade -- take labor and subjectivity out of the dept.



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Key Points Discussed		
No.	Topic	Highlights
1	Napoleon's overview	High level overview of customers (Wholesalers, distributors and chains) Walgreens, CVS & Rite Aid main chains. Amerisource/Bergen, McKesson – main wholesalers. Cardinal Health handles indirect chain accounts, and regular and national distributors such as Anda, Premier, and HD Smith. Approx. 85% of our distributors go through Gurnee.
2	Bob's overview DEA	DEA plays by their own rules. Shoot first and ask questions later. They have a tendency to interpret the regs. the way they want to and have been successful being aggressive against companies. Bob requested a list of all our customers from Napoleon – discussed customers and would also like a list of all our List I chemical customers.
3	How things currently work and problems surrounding it	Larry's presentation focused on our systems flow chart. – Discussion continued on the various codes used and the collaborative review process and procedures. Reviewed EDI process, orders and pends, end of month and holiday trends, and also number of Monday's in a month as they pertain to ordering patterns. Point of review – only if flagged. Customer would be called. Sandy mentioned how many times a customer was surprised that we were calling. Also people in purchasing order on demand principles not by compliance regulations. Very big disconnect in some companies. Bob was impressed and stated that all organizations do not have all depts. working together like Watson!
4	Problems	Jonathon had some questions and concerns. 1 – Found behaviors that have to be adjusted. 2- How are we tracking the information? Statistical challenge. What are we doing with the information when we discover it? 3 – Down the road we will be able to add notes etc. Mary stated we don't modify – Cancel never adjusted orders ???? Jon stated some diversion better than no diversion????? SAP has an audit log that modifies behind the scenes.
5	OMS & SOMS	Napoleon's group controls the OMS. (Order Management system). Napoleon checks on allocations and who is entitled. SOMS no partials. OMS pend comes before SOMS pend. Inventory goes through stages – Marketing - purpose review first, then system decides if order is in violation.

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6	Jonathon's discussion	<p>Track on face off page. Comment on interface page. Transfer to intelligent algorithm. Concerned about other bottle strengths on order (increase) – currently we cancel one line that would pend, but send out rest of the order with 4 other strengths of the same product on same order. Whole spectrum of intelligence of crooks statistically modifies orders. Stopping just one size may be tipping off customers. Catching the action but missing the majority of the movement.</p> <p>Also, multiplier based on class of trade was another issue.</p> <p>Scott asked what the risk to us would be and if we were meeting the criteria? Jonathon responded that we did not identify that issue...by stopping one line and letting all the other ones go through were not in compliance with DEA. The whole product family on the order would need to be reviewed - algorithm. Our way would not make sense to DEA – Plausible deniability. DEA cares about the whole package. Having lots of little orders is the problem.</p> <p>His solution would be to recategorize the order by mgs. (total order) DEA doesn't care about the NDC - better to evaluate by total milligrams. (mgs. strength)</p> <p>Good news with doing it his way - denominator much larger, false positive drops, sensitivity better. Doing it by family – stops multiple times checking order and stops as many orders pending. The system would generate/calculate the mgs. for you based on overall active ingredient. You can add weight as well to individual drugs by specific NDC's and lots in algorithm. The system looks at it differently. Superior approach milligram quantity – preferred DEA model.</p> <p>Noticed while reviewing records on Florida customers, those who ship direct to pharmacies, he noticed that our NDC's are very prevalent. Georgia and Houston as well.</p> <p>Two states on the radar now – KY and NV – statistically per capita the worse. (Also FL and TX)</p> <p>Medicaid providers (PBM) studying pain management.</p>
7	Bob's discussion	<p>DEA wants performance based approach. Statistically defensible model. Uses language in regulations – Sept. 2007 letter. No clients ever called Bob's organization questioning the SOMS Program. DEA satisfied with overview never asked about logic. Formula alone will not keep you out of trouble. DEA has investigations and audits. SOMS goal has to be a reasonable and thoughtful attempt.</p> <p>Arcos data and trending – per capita consumption by zip code. DEA will pull this information up. (Lenny Levine and Jim Arnold's group)</p>
8	Larry's SOMS examples	<p>Larry provided examples of why orders pend or are blocked for different reasons. Included discussion on VMI, EDI and demand management process</p>
9	Lisa Scot	<p>We call the pending orders in SOMS – "orders of interest". We only reported one suspicious order to Chicago field office. - Dixon Shane. Our orders are customer specific – they need to justify why they need the product. By providing customer lists, orders, etc. DEA Affairs group makes decision on whether to approve the quantities after researching.</p>

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10	Issues to be addressed	<p>Price increases – Jon – can check another box to not consider these types of orders for future thresholds.</p> <p>Seasonal spike on products – Pseudoephedrine products</p> <p>New launches- falsely inflated numbers – the algorithm would not be driven by specific 1st buy in. New NDC would be using active ingredient – can go online instantly.</p> <p>New customers- new products added to contracts.</p>
11	Justin Park – Technical IT	<p>Justin provided the technical SOM logic flow charts and history of how orders flow through different areas before they pend to SOMS. e.g. – Sample orders wouldn't go through SOMS system. Pseudoephedrine orders only goes through licensing pend not SOMS. ****This would need to be addressed in the new system.</p> <p>There are 13 different release codes for SOMS orders.</p> <p>Jonathon – the first moment of change is where you should detect unexplainable change not behavior regardless of what it is. Historical markers – acquisition of better collection of those markers. (Don't use algorithms) Need to think how to build markers (statistics) what would be a marker if this changed an incident. Get to adaptive algorithm.</p>
12	Mary Woods – CS Processes	<p>On-boarding process and customer vetting handled by Mary's group. Mary to supply perspective qualifying questionnaire to Cegidim.</p> <p>Mary discussed process and flow starting with initial request which would come from the Directors of National Accounts. Uses NTIS and DEA website to verify legitimacy of customers. Visit corporate offices – currently do not visit physical shipping locations. Also, does independent internet researches on clients. Bob suggested that they should also include research on their principle owners and corporate officers. Mary said we require financials and that information is included sometimes.</p> <p>Bob suggested we should have a separate compliance agreement form – When sign on new accounts we should have then sign and attest to what the controlled substances are used for and that they have SOMS program and follow all procedures accordingly. Mary to relay to Kathleen Karlsson to add to pricing agreement that they follow all SOMS, Security policies of Watson and CFR. They should also represent to Watson and confirm in writing that they do this and only distribute controlled substances for legitimate medical reasons.</p> <p>Currently we do not have any visits to customers when orders pend.</p> <p>We have approx. 300 corp. entries or 1500 existing ship to locations. SOMS – 80% will purchase controlled substances.</p> <p>Mary noted that we have over 800 products and new customers must commit to purchasing at least 100 skus. Jonathon suggested that with ongoing customers that we can add some markers such as what percentage purchased is controlled, if we hold them to their contracted numbers. Marketing evaluates the contracts each year. After qualifying questionnaire Customer Support is no longer responsible. Accountability goes to Marketing, Contracts and VP of Sales.</p>

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13	Orders	<p>How many ways are orders placed?</p> <p>EDI – Electronic Data Intercheck – system interfaces our system with customer system- maps data. PO developed and interchanged to our system. Our system confirms receipt of PO.</p> <p>Fax – manual order</p> <p>e-mail</p> <p>verbal</p> <p>VMI – Vendor Management Inventory (e.g.- co-manage customers inventory – Wal-Mart)</p> <p>C2 orders – mail</p> <p>CSOS – electronic</p>
14	IMA/OMS/SOMS	<p>IMA and OMS - both validations occur in current system before SOMS validation.</p> <p>IMA – issue shows clear inventory need however what type of scrutiny is done on IMA or EDI orders? Jonathon said that when using algorithms they learn to adapt to each type of order. A mechanism is created to have them operate differently. We should call this "<u>Suspicious Inventory Monitoring</u>" He also said it is easier to build monitors around the inventory than the orders.</p> <p>They requested a list of IMA customers. IMA agreement in contract – Preferred customers – ship product only to them when shortage. IMA is under the direction of Rose Bentrovato's group as they set the parameters for the customers for weeks on hand inventories.</p>
15	Suggestions	Bob suggested that we need to incorporate list I chemicals in the SOMS program because DEA handles these products like schedules 3, 4, & 5.
16	SOP's	Bob would like a copy of the SOP's for SOMS and any presentations – supply electronically.
17	Path Forward	<p>Evaluation – 10 working days. Bob reviews everything with Ron Buzzeo. All communication will go to Tom and Scott. They recommended that the SOMS and Compliance Regulation issues tie into legal.</p> <p>Future – Compliance, Remove labor intensity, and automation.</p>
18	Next Phases	<p>Phase I - Evaluation - Audit Report</p> <p>Phase II – Develop Algorithm – Proposal (Budget planning meeting – estimate)</p> <p>Phase III – Implementing</p>

Action Plan

No.	Action Item	Owner	Target Date
1	List of Customers – Napoleon	Napoleon	
2	Perspective Qualifying Form - CSS	Mary	
3	List of IMA Customers	Mary	
4	Copy of SOP's for SOMS and presentations from meeting	Lisa/Tom	